

Message

From: Kurt Straif [StraifK@iarc.fr]
Sent: 4/1/2016 7:11:25 AM
To: Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]
Subject: RE: News Update: Johnson & Johnson Has a Baby Powder Problem - More than 1,000 women are suing the company for covering up a cancer risk (Bloomberg)

Thank you Vincent;

PBI / Ex. 4

Warmest regards,
Kurt

From: Cogliano, Vincent [mailto:cogliano.vincent@epa.gov]
Sent: 01 April 2016 02:05
To: Kurt Straif <StraifK@iarc.fr>; Kathryn Guyton <GuytonK@iarc.fr>; Neela Guha <guhan@iarc.fr>; Dana Loomis <LoomisD@iarc.fr>; Baan Robert <robert.baan@69lyon03.org>; Grosse Yann <grosse@iarc.fr>; Beatrice Lauby-Secretan <secretanb@iarc.fr>; El Ghissassi Fatiha <ElGhissassi@iarc.fr>; Bouvard Véronique <bouvard@iarc.fr>; Lamia Tallaa <tallaal@iarc.fr>; Lorenzen-Augros Helene <lorenzen@iarc.fr>; Gaudin Nicolas <gaudin@iarc.fr>
Subject: Fwd: News Update: Johnson & Johnson Has a Baby Powder Problem - More than 1,000 women are suing the company for covering up a cancer risk (Bloomberg)

PBI / Ex. 4

Begin forwarded message:

Subject: News Update: Johnson & Johnson Has a Baby Powder Problem - More than 1,000 women are suing the company for covering up a cancer risk (Bloomberg)

Johnson & Johnson Has a Baby Powder Problem
More than 1,000 women are suing the company for
covering up a cancer risk.

By Susan Berfield, Jef Feeley, and Margaret Cronin Fisk | March 31, 2016
Photograph by Travis Rathbone

From

Jacqueline Fox worked in restaurant kitchens and school cafeterias, cleaned people's houses, watched their kids, raised a son, and took in two foster children. She was careful about her appearance and liked to tend the garden in front of her home in Birmingham, Alabama. She had been treated for high blood pressure, arthritis, and diabetes, but, at 59, she was feeling pretty good. In the spring of 2013, her poodle, Dexter, began acting strangely. He'd jump on her, he'd cry, he'd stay close by all day. Fox happened to watch a television program about a dog that sensed its owner was unwell. When she let Dexter sniff her, he whined even more.

A week later, Fox was diagnosed with advanced ovarian cancer. She had chemotherapy to shrink the tumors and surgery to remove her uterus, ovaries, fallopian tubes, and part of her spleen and colon. In December of that year, she saw a commercial from an Alabama law firm, Beasley Allen, suggesting a connection between long-term use of Johnson & Johnson's Baby Powder and ovarian cancer. Fox had been sprinkling Baby Powder made from talc on her underwear every day since she was a teen. "I was raised up on it," she later said in a deposition. "They was to help you stay fresh and clean. ... We ladies have to take care of ourselves." It was as normal as using toothpaste or deodorant. "We both were a bit skeptical at first," says her son, Marvin Salter, a mortgage banker in Jacksonville, Fla. "It has to be safe. It's put on babies. It's been around forever. Why haven't we heard about any ill effects?"



Fox and Salter in June 2014.

Source: Fox Family

Fox died from the cancer in October 2015. Four months later, a jury in St. Louis concluded that talcum powder contributed to the development of the disease and that Johnson & Johnson was liable for negligence, conspiracy, and failure to warn women of the potential risk of using Baby Powder in the genital area. The verdict, decided by a 10-2 vote, included \$10 million in compensatory damages and \$62 million in punitive damages, more than Fox's lawyers had recommended. Salter bowed his head and wept.

"People were using something they thought was perfectly safe," he says. "And it isn't. At least give people the choice. J&J didn't give people a choice." Among the most painful revelations, he says, was that in the 1990s, even as the company acknowledged concerns in the health community, it considered increasing its marketing efforts to black and Hispanic women, who were already buying the product in high numbers. Fox was black. The jury foreman, Krista Smith, says internal documents provided the most incriminating evidence: "It was really clear they were hiding something." She wanted to award the Fox

family even more. Imerys Talc America, the biggest talc supplier in the country and the sole source of the powder for J&J, was also named as a defendant. The company wasn't found liable.

"Jury verdicts should not be confused with regulatory rulings or rigorous scientific findings," Carol Goodrich, a spokeswoman for Johnson & Johnson Consumer, said in an e-mail. "The overwhelming body of scientific research and clinical evidence supports the safety of cosmetic talc." The company says it will appeal the verdict. In a statement, Imerys said it's "confident that its products are safe for use by its customers. Our confidence is supported by the consensus view of qualified scientific experts and regulatory agencies."

Johnson & Johnson has spent more than \$5 billion to resolve legal claims over its drugs and medical devices since 2013. That year, it agreed to pay \$2.2 billion to settle criminal and civil probes into claims that it illegally marketed Risperdal, an antipsychotic drug, to children and the elderly; two other medicines were included in the settlement. It was one of the largest health fraud penalties in U.S. history. The company has also agreed to pay some \$2.8 billion to resolve lawsuits about its artificial hips and \$120 million for faulty vaginal-mesh inserts. In its 2015 annual report, J&J stated that more than 75,000 people had filed product liability claims, and that didn't include the talc powder cases.

More than 1,000 women and their families are suing J&J and Imerys, claiming the companies have known of the association with ovarian cancer for years and failed to warn them. The next trial is scheduled to begin on April 11 in a St. Louis circuit court. "Whether or not the science indicates that Baby Powder is a cause of ovarian cancer, Johnson & Johnson has a very significant breach of trust," says Julie Hennessy, a marketing professor at Northwestern's Kellogg School of Management. "In trying to protect this one business, they've put the whole J&J brand at risk."

"It has to be safe. It's put on babies. It's been around forever. Why haven't we heard about any ill effects?"

Talc is the softest mineral on earth, able to absorb odors and moisture. It's composed of magnesium, silicon, and oxygen and is mined, usually from deposits above ground, in

more than a dozen countries. It's used in eye shadow and blush and chewing gum, but mostly it's used in ceramics, paint, paper, plastic, and rubber. China is the biggest source; Johnson & Johnson's supply comes from the southern province of Guangxi.

Johnson & Johnson began selling Baby Powder more than 100 years ago, soon after the company was founded in New Brunswick, N.J. Among its first products were adhesives infused with pain relievers such as mustard seed, capsicum, quinine, and opium. When customers complained that removing the plasters left them with skin irritation, J&J's scientific director sent them small containers of talc to help soothe any rashes. A few reported that the talc also seemed to ease diaper rash. In 1894 the company introduced Baby Powder, made of 99.8 percent talc and sold in a metal tin labeled "for toilet and nursery."


The other 0.2 percent is a mix of fragrant oils. Smell is evocative, and this particular scent is mingled with powerful memories—a marketer's dream. "It's calming, nurturing. ... It doesn't grab your senses. It wafts," Fred Tewell, a J&J executive, told the Associated Press in 2008. The company has said that in blind tests, the scent of Baby Powder is recognized more often than that of chocolate, coconut, or mothballs. From the early 1900s, J&J tried to persuade women to use the powder on themselves, too. Ads in 1913 included the tag line, "Best for Baby, Best for You." By 1965, when Fox was 12 years old, ads featured a sultry woman sprinkling talc on her bare shoulder. No baby is in sight. "Want to feel cool, smooth and dry? It's as easy as taking powder from a baby." Two decades later, the company told the New York Times Magazine that 70 percent of its Baby Powder was used by adults. Sales of J&J's talcum powder products came to about \$374 million in 2014, according to Euromonitor. That's not essential to a \$70 billion company that makes most of its money selling medical devices and drugs. But without Baby Powder, J&J may not have developed Baby Oil or Baby Shampoo nor have a baby division worth some \$2 billion. Baby Powder's value to the company extends well beyond sales.

Forty-five years ago, British researchers analyzed 13 ovarian tumors and found talc particles "deeply embedded" in 10. The study, published in 1971, was the first to raise the possibility that talcum powder could pose a risk. In 1982 a study in the journal *Cancer* by Daniel Cramer, an epidemiologist at Brigham & Women's Hospital in Boston, showed the first statistical link between genital talc use and ovarian cancer. Soon after, Cramer received a call from Bruce Semple, an executive at J&J. The two met in Boston. "Dr. Semple spent his time trying to convince me that talc use was a harmless habit, while I

spent my time trying to persuade him to consider the possibility that my study could be correct and that women should be advised of this potential risk of talc,” Cramer, a paid expert and witness for the plaintiffs, said in a 2011 court filing. “I don’t think this was a question of money,” he says now. “I think it was pride of ownership. Baby Powder is a signature product for J&J.”

Baby Powder is considered a cosmetic, which doesn’t need to be approved by the Food and Drug Administration under the 1938 Food, Drug, and Cosmetic Act. The law is laid out in a 345-page document; only two pages are devoted to the safety of cosmetics. Congress is considering updating the law to give the FDA more authority to regulate products. “It shouldn’t be up to consumer groups or jurors to try to make decisions about toxic products,” says Stacy Malkan, co-founder of the Campaign for Safe Cosmetics. J&J and many other big companies support the changes.

J&J does have a warning on Baby Powder, cautioning against inhalation. And the label notes that the powder is for external use only. Under pressure from consumers, activists, and impending California safety regulations, J&J has removed triclosan, formaldehyde, and other so-called chemicals of concern from its baby products in the past few years. In 2013, Samantha Lucas, a company spokeswoman, explained the shift to Scientific American: “We’ve been replying with evidence of the science that ensures safety. Now we have to go beyond science and be responsive to our consumers, because it’s really about their peace of mind.” If J&J applies this same thinking to Baby Powder, it has an alternative: It already sells Baby Powder made from cornstarch for about the same price. No study shows that cornstarch poses any potential risks; the American Cancer Society has been suggesting since 1999 that women consider it if they want to use genital powder. Some of J&J’s competitors, including Gold Bond, California Baby, and Burt’s Bees, sell baby powder made of cornstarch only.



Since Cramer’s article was published, an additional 20 epidemiological studies have found that long-term perineal talc use increases the risk of ovarian cancer by about 33 percent. Yet other research has found no association. These mixed results have been cited by many agencies and institutions—with the exception of the International Agency for Research on Cancer (IARC) at the World Health Organization—when they’ve looked at a potential link.

Roberta Ness, former dean of the University of Texas School of Public Health and former president of the American Epidemiological Society, testified at the Fox trial as an expert witness for the family. She argued that several of the studies showing no link didn't properly measure women's exposure to talcum powder. Some asked women how many years they had used the powder; others asked how often they used it. Only five measured both. "What's confused everyone in the past," she said during the trial, is that "all these studies, they looked at just frequency or just duration, and they're all over the map." She went on to explain that "all of the studies that have actually measured frequency and duration ... have all shown a statistically significant trend toward more exposure causing more disease." Ness pointed out that the association between hormone therapy and breast cancer is statistically smaller than the reported association between talc and ovarian cancer, yet hormone therapy is considered to be a real risk.

She also said that not being able to prove how talc powder could contribute to cancer doesn't relieve a company of the responsibility to warn women of the association. "We now have data that suggest there's an association between the Zika virus and microcephaly," she said. And even though scientists don't know how the virus causes the disease, "people aren't waiting. ... People are out there saying, 'Oh my gosh, be aware, this is trouble.'"

J&J and Imerys, the talc supplier, argue that the statistical associations between use of the powder and ovarian cancer are limited, weak, and based on unreliable data. They say a causal link isn't biologically plausible, because there's no proof that talc particles can move up through the reproductive tract or that once there they could cause cancer. And if there's no causal connection, they say there's no reason to add a warning to Baby Powder. "There are statistical correlations. You can always calculate correlations," says Joshua Muscat, a professor of public health sciences at Penn State College of Medicine who serves as an expert consultant to J&J. "There hasn't been a single scientific body that has considered talc to be a causal agent. Many don't even consider talc to be a risk factor. To me, the science is black and white."

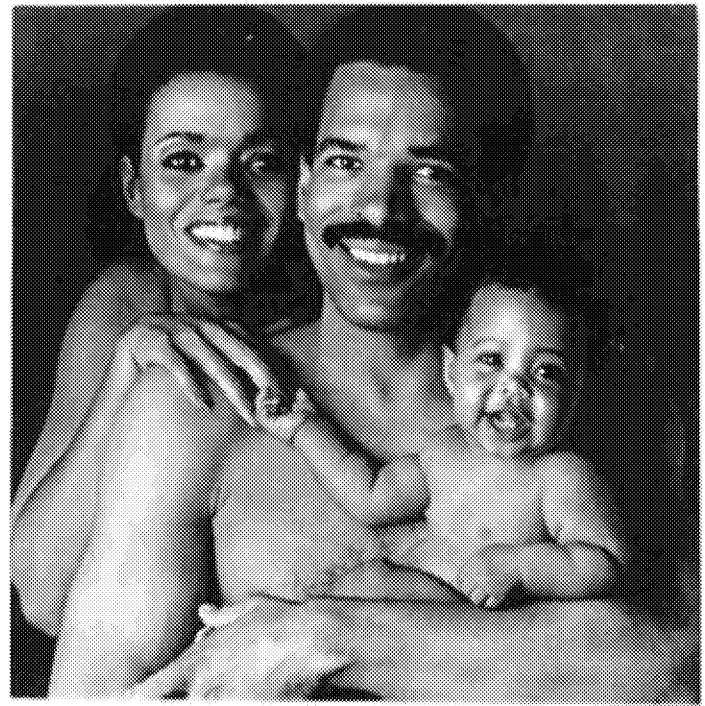
The odds of a woman in the U.S. falling ill with ovarian cancer are 1 in 70. Talc use is associated with worse odds, 1 in 53, according to those epidemiological studies. The risks seem to be higher for invasive serous cancer, which Fox had. Ovarian cancer is among the most deadly cancers. Some 20,000 women are diagnosed each year, often after the disease has spread. The symptoms are easily dismissed as menstrual or abdominal discomfort. There's no regular screening for ovarian cancer, no known causes, only risk factors, and

some research suggests the malignancy may begin outside the ovaries, at the end of the fallopian tubes. More than 14,000 women die from the disease every year.

At the Fox trial, Ness did some harsh math for the jury. She claimed that Baby Powder use could contribute to some 2,500 women being diagnosed with ovarian cancer every year and 1,500 dying. The defense counsel, with great skepticism, called that figure “astonishing.” Ness also noted that although black women generally have lower odds than white women of getting ovarian cancer, a small study recently showed they’re more at risk of developing ovarian cancer when exposed to talc.

In the last months of her life, Fox answered questions from attorneys on both sides of the case. The audio of her deposition was played in the courtroom near the end of the three-week trial. When asked why she was suing J&J, she said, “To put out there that we as women got to take care of ourselves. This is a disease I didn’t ask for. But who am I? I just want to do right.”

The science may be limited, and it may be ambiguous. Many of the researchers involved, including Cramer, say more study is necessary. But the science wasn’t on trial in St. Louis; Johnson & Johnson was. “You don’t win with jurors on science. They don’t understand science, statistics, the design of studies,” says Erik Gordon, a professor at the School of Business and School of Law at the University of Michigan. “They do understand there was some evidence of a connection between talc and cancer, and J&J didn’t tell customers about it.”



Think of us as a lifetime friend of the family.

A friendship with a Johnson's baby product begins when you're born and grows with time. All those good, comfortable feelings you feel when you were young stay with you as an adult. Every member of the family enjoys sharing the clean, baby-soft skin of your baby with Johnson's Baby Powder. Johnson's Baby Lotion helps keep everyone skin soft and smooth.



Johnson's Baby Shampoo, with its 'No More Tears' formula, is a friend to babies' eyes and noses. Everyone's hair grows, looking it with a healthy natural shine. And Johnson's Baby Oil not only helps take care of your baby in lots of ways, it also works as a wonderful beauty oil for you. Johnson's baby products. What you make us a friend, we'll be.

J&J ads from 1965 and 1980.

Ebony magazine ad: Gaslight Ad Archives

Lawyers for Fox introduced documents from 1986 through 2004 that, however selective they may be, portray a company struggling to revive interest in a symbolically important product with no proven health benefits and some suspected health risks. A 1992 memo outlining “major opportunities and major obstacles” acknowledged that “negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage) continues.” The same memo included a recommendation to “investigate ethnic (African-American, Hispanic) opportunities to grow the franchise,” noting that these women accounted for a high proportion of sales. An added handwritten note says the company planned a print advertising campaign. Goodrich, the J&J spokeswoman, said in her e-mail that this was “simply part of the company’s efforts to appropriately understand who is using its products.” More than a decade later, a task force devoted to improving sales of Shower to Shower, a mix of talc and cornstarch marketed to women, concluded: “African American consumers in particular will be a good target with more of an emotional feeling and talk about reunions among friends, etc., team up with *Ebony* Magazine.” It suggested promotions in churches, beauty salons, and barbershops, and Patti LaBelle or Aretha Franklin as celebrity endorsers. Neither became

a spokeswoman for the brand. It's not clear how much of the rest of the plan was put into action, since the company had already been advertising to blacks.

It's standard practice for companies to focus on their most committed customers. Airlines take care of business fliers; loyal shoppers get special deals at stores. "That's probably what they were doing," says Hennessy, the Kellogg marketing professor. "In today's climate, though, that looks horrible. From the outside it looks like J&J is less concerned, not more concerned, about its most loyal users because of their ethnic origin."

Baby Powder is a legacy brand in the black community. "Some people might say, 'What's wrong with companies recognizing women of color as important consumers?'" says Robin Means Coleman, a professor of communications studies and Afro-American Studies at the University of Michigan. "We do want that. But we do not want companies to market potentially carcinogenic products."

Salter, Fox's son, hadn't been aware of the marketing documents until the trial. "When I heard about it, I was infuriated," he says. "And so was the jury."

In the 1990s a toxicologist named Alfred Wehner worked as an outside consultant for J&J. His official role was to help evaluate the research on ovarian cancer and talc and advise the company on its response. Unofficially, he was its scold. Wehner was on J&J's side, but he was concerned that a cosmetics trade group (partly funded by the company) was mischaracterizing the scientific case for talc. "A true friend is not he who beguiles you with flattery but he who discloses to you your mistakes before your enemies discover them," Wehner began a [1997 letter](#) to Michael Chudkowski, J&J's manager of preclinical toxicology. Wehner described statements on talc research from the group as inept, misleading, and outright false. Referring to a statement a few years earlier, he wrote: "At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary." He wanted the trade group to argue that the studies' biological significance was questionable.

Cosmetic talc isn't a big part of Imerys's business. The company, formerly called Luzenac, primarily sells the mineral for industrial purposes. But until 2006, it also fought any

suggestion that talc could be a potential carcinogen. In the late 1990s, according to a Luzenac memo introduced at the trial, executives visited the head of epidemiology at the University of California at Irvine for advice on how “to stop the rumor about Ovarian cancer.” One suggestion: Get “two or three experts from the club” to make the scientific case. “The club” could refer to independent scientists Luzenac had worked with before, but Fox’s lawyers argued for a more sinister interpretation—that these were scientists who would respond to industry pressure. They also suggested that Luzenac and J&J exerted influence over a government group. In 2000 scientists with the National Toxicology Program, part of the U.S. Department of Health and Human Services, voted 13-2 to list talc, used perineally, as a possible human carcinogen, according to Fox’s lawyers, but the companies persuaded the NTP to defer an official decision on the status of talc. A Luzenac executive, Richard Zazenski, wrote to a colleague afterward: “We, the talc industry, dodged a bullet in December, based entirely over the confusion of the definition issue.” He was referring to ambiguity over the composition of the talc studied because, until the early 1970s, some powder contained naturally occurring asbestos fibers. He also discussed a coming NTP review, saying, “Time to come up with more confusion!” Imerys declined to comment on the specifics of the trial, but one witness for the defense offered the possibility that Zazenski was joking. Goodrich, the J&J spokeswoman, said any suggestion by Fox’s lawyers of improper influence is “merely an unsubstantiated allegation.”

In 2006, the IARC, the WHO cancer agency, declared that perineal use of cosmetic-grade talc was possibly carcinogenic. It cited “a modest, but unusually consistent, excess in risk” and also noted that bias in the studies couldn’t be ruled out. Publicly, Luzenac and J&J tried to diminish the significance of the designation; red meat and coffee are also included in this group of possible carcinogens.

Before the year ended, however, Luzenac stopped backing studies to prove talc’s safety because the “horse has already left the barn,” wrote one executive, noting that cosmetic companies had also cut funding. One of their primary arguments for doing so, he said, was that there were already too many studies showing an association with ovarian cancer “to stem the tide of negative sentiment.” More important, Luzenac added a warning on the safety data sheet included with the 2,000-pound bags of talc it delivers to J&J: Perineal use of the powder is a possible risk factor for ovarian cancer.

“We, the talc industry, dodged a bullet in December. ... Time to come up with more confusion!”

Johnson & Johnson says it will continue to defend the safety of talc, and it does so on its website. There, in a section explaining its policies about ingredients, the company addresses concerns over formaldehyde, parabens, phthalates, and triclosan—chemicals with damaged reputations, and worse. In every case, J&J states that the chemicals haven’t been proven harmful or that they were used in small enough amounts to be safe, but the company decided to remove them from its products anyway. “We understand that from your perspective, government regulations may not be your only consideration when it comes to the personal-care products you and your family use,” it says about parabens. For phthalates, the company says it recognizes that “the best way to keep your confidence was not to use it at all.”

Why not apply that same standard to talc? Goodrich said the company listens when consumers raise concerns about ingredients. But “few ingredients have the same demonstrated performance, mildness and safety profile as cosmetic talc.”

The first woman to sue Johnson & Johnson for not warning of the risks of talcum powder was Deane Berg, who was diagnosed with ovarian cancer in 2007. She says she turned down a \$1.3 million out-of-court settlement because she didn’t want to sign a confidentiality clause. Her case went to trial in 2013 in a South Dakota federal court as she was in remission. The jury found J&J was negligent, but didn’t award Berg any damages.

After the Fox verdict, 17,000 people contacted her attorneys at Beasley Allen; the firm is looking into 2,000 of those, in addition to 5,000 potential claims it was already investigating. Its next case will be tried in the same St. Louis circuit court as Fox’s, which has a reputation for being sympathetic to plaintiffs. Gloria Ristesund’s trial is set for April. She used Baby Powder for 40 years and was diagnosed with ovarian cancer in 2011.

Among those waiting their turn is Tenesha Farrar, who was diagnosed with Stage 3 ovarian cancer in 2013 and is represented by the Lanier Law Firm. Farrar, who’s 40 and black, says she’d used Baby Powder and Shower to Shower (which J&J sold to Valeant in

2012) for the last two decades. “My grandmother and mother used it, and I learned from them,” she says. After hearing about the J&J marketing document, she began crying. “I can’t believe they singled us out.” Farrar had chemotherapy and a full hysterectomy. She had to take off five months from her work as a clerk in a dialysis clinic outside St. Louis. She lost her health insurance because she exceeded the policy limits and had to skip her last chemo treatment. She and her husband eventually filed for bankruptcy. She’s back at work now. “I have five children who depend on me,” she says. “I will never use another J&J product again.”

(Corrects the year that the Ebony magazine J&J ad ran.)

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